

**UNITED STATES DEPARTMENT OF COMMERCE****Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Thru

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/156,952	09/18/98	OSTGAARD	R CYM-U25

021323
TESTA HURWITZ & THIBEAULT
HIGH STREET TOWER
125 HIGH STREET
BOSTON MA 02110

IM22/0908

EXAMINER	
BEX, P	
ART UNIT	PAPER NUMBER
1743	10
DATE MAILED: 09/08/00	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/156,952	Applicant(s). Ostgaard et al.
	Examiner Patricia Kathryn Bex	Group Art Unit 1743

Responsive to communication(s) filed on Jun 13, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

Claim(s) 1-25 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

Claim(s) _____ is/are allowed.

Claim(s) 1-25 is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

-- SEE OFFICE ACTION ON THE FOLLOWING PAGES --

Art Unit: 1743

DETAILED ACTION

Claim Rejections - 35 U.S.C. § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites the use of an “anti-torque” lug on the body outer surface of a sample vial. However, as disclosed in the specification on page 18, lines 23-26 “the anti-rotation lugs are adapted for use with storage tray and/or vial sleeve to prevent the rotation of the body”. Therefore, it is vague and indefinite as to how the “anti-torque” lugs perform the “anti-rotation” without a storage tray and/or vial sleeve.

Claim Rejections - 35 U.S.C. § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 1743

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 1-23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Julian (USP 3,825,143).

Moore teaches a sample vial for use in an automated test apparatus comprising a body with an outer surface, an open end, a closed end, a cap 34 releasably engagable with the body, the cap comprising an outer surface and a torque pattern (Fig. 1 & 3) on the cap outer surface, the torque pattern comprising a plurality of radially disposed ribs 64, and seals 54, 98 disposed between the body and the cap so as to be capable of forming a substantially fluid-tight seal therebetween. Moore does not teach the use of at least one anti-torque lug about the body outer surface. However, Julian does teach the use of at least one anti-torque lug 19 about the body outer surface (column 2, lines 18-37, Figs. 1-6).

Accordingly, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have included in the sample vial of Moore the lugs as taught by Julian, in order to ensure that the cap remains tightly in place on the container and cannot be removed even by carrying out the unexpected movement (column 1, lines 2-38).

Art Unit: 1743

Moore teaches sample fluid level indicia 108 comprising an upper fill line and a lower fill line on the outer surface of the vial body (Fig. 1).

Moore teaches a first alignment marker 110 on the body on the cap and a second alignment marker 108 on the body (column 7, lines 24-40).

Moore teaches a cap comprising first screw threads 62 (Fig. 4) and a second mating screw thread 80 on the body (Fig. 1).

Moore does not explicitly teach the use of the body and cap made from polypropylene, ^{it} however would have been obvious to one having ordinary skill in the art at the time the invention was made to have made the body and cap from an inert material, such as polypropylene, in order to ensure that the sample inside the vial will not react with the container or cap. Further, it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Moore teaches a fluid-tight seal formed between the body and the cap (column 6, lines 41-61). However, Moore does not disclose the range of torque between 5 and 50 inch-pound of torque applied to the cap. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have included in the invention of Moore the range of torque between 5 and 50 inch-pound of torque applied to the cap in order to ensure the cap and vial are properly sealed and prevent the leakage of a sample or air from the vial. Further, it has been held

Art Unit: 1743

that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

6. Claim 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moore (USP 5,855,289) in view of Julian (USP 3,825,143), as applied to claim 23 above, and further in view of Neeley *et al* (USP 5,164,575).

Moore and Julian as previously discussed, do not teach a sample indicia comprising a bar code. However, such a means for identifying kinds of sample vials is considered conventional and usually required in the automatic analyzing art, see Neeley *et al*. Neeley *et al* teaches a sample indicia comprising a bar codes 7 & 51 (column 6, lines 46-68, Figs 4-5 & 8).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided in the modified apparatus of Moore, a bar code on the sample vial, as taught by Neeley *et al*, in order to identify the sample and make sure the proper sample is matched up with the patient (columns 2-3).

Response to Arguments

7. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection. See above Office Action.

Conclusion

8. Claims 1-25 are rejected.

Art Unit: 1743

9. References McFadyen and Gach are cited as art of interest for the teachings of a sample vial comprising a body comprising a cylindrical outer surface, an open end, a closed end, and a cap releasably engagable with the body and a seal disposed between the body and the cap.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Kathryn Bex whose telephone number is (703) 306-5697.

The fax number for the organization where this application or proceeding is assigned is (703) 305-7718 for official papers prior to mailing of a Final Office Action. For official papers after mailing of a Final Office Action, use fax number (703) 305-3599. For unofficial or draft papers use fax number (703) 305-7719. Please label all faxes as official or unofficial. The above fax numbers will allow the paper to be forwarded to the examiner in a timely manner.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0661.



Patricia K. Bex
Patent Examiner
AU 1743
August 28, 2000


Jill Warden
Supervisory Patent Examiner
Technology Center 1700